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| EXAMINER | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/814,620 | TZIANABOS ET AL. | |
| | Examiner | Art Unit | |
| | NORA M. ROONEY | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,17,18 and 98-102* is/are pending in the application.

4a) Of the above claim(s) *98-100 and 102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,17,18 and 101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/25/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. Applicant's replies filed on 11/19/2007 and 03/19/2008 are acknowledged.

2. Claims 1-7, 17-18 and 98-102 are pending.

3. Applicant's election without traverse of the species urticaria in the reply filed on 03/19/2008 is acknowledged.

4. Claims 98-100 and 102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/19/2008

5. Claims 1-7, 17-18 and 101 are currently under examination as they read on a method for treating urticaria comprising administering PSA1 to a subject.

6. Applicant's IDS documents filed on 06/25/2007 is acknowledged.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-7, 17-18 stand rejected and claim 101 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for a method for treating **an allergic condition other than asthma** in **a subject**, comprising: administering to **a subject** having **an allergic condition other than asthma an isolated polymer** in an effective amount to treat the allergic condition, wherein the polymer **comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate** of claim 1; wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate of claim 2; wherein the administering comprises **delivering an aerosol of the polymer to an airway of the subject** of claim 3; wherein the subject is **free of symptoms otherwise calling for treatment with the polymer** of claim 4; wherein the polymer is **a polysaccharide** of claim 5; wherein the polymer is **a bacterial capsular polysaccharide** of claim 6; wherein the polymer is PSA1 of claim 7; wherein the method further comprises administering to **the subject** an anti-allergy medicament selected from the group consisting of glucocorticoids, antihistamines, and **anti-IgE** of claim 17; wherein the administering comprises administering to **the subject** having **an allergic condition other than asthma** multiple doses of the **isolated polymer** to treat **the allergic condition** of claim18; and wherein the **allergic condition other than asthma is urticaria** of claim 101. The specification disclosure does not enable one skilled in the art to practice the invention without an

undue amount of experimentation for the same reasons as set forth in the Office Action mailed on 05/18/2007.

Appliant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

"Applicant respectfully submits that allergic diseases, despite their differences, are complex biological phenomena that are widely recognized to share certain common underlying features, namely, a skewing toward a Th2 character at least in their initial phase of disease. As allergic diseases become more chronic, they can evolve to have more of a Thl character. In any case, if the initial Th2 phase can be treated, then allergy and evolution toward more Thl character can be averted. In addition, treatments that dampen both Th2 and Thl immune responses are, not surprisingly, described to be effective for treating allergic diseases. Studies relating to the administration or neutralization of individual cytokines are generally not particularly instructive because allergic diseases are the outward manifestations of both cooperative and competing immune responses involving a wide array of cell types and signals.

On page 5 of the Office Action the Examiner points to the teachings of Hertl et al. (2000) *Allergy* 55:108-15 for the proposition that nickel allergic individuals have exhibited Thl, Th2, and Th0-type cells producing both Thl and Th2 cytokines during the course of allergic disease. The mere observation, however, that there may be Thl and Th0 cells, in addition to Th2 cells, or that there may be Thl cytokines, in addition to Th2 cytokines, in an allergic disease does not necessarily mean that the skewing of an immune response toward Thl may not be effective for treating the allergic disease. In addition, the instant disclosure also teaches that the polymers of the invention induce proliferation ofT regulatory cells (see, for example, page 23 of the specification), and such T regulatory cells are further disclosed to downregulate an immune response. Such downregulation would affect Thl, Th2, and Th0 cells. Accordingly, the teachings of Hertl et al. do not support the suggestion by the Examiner that the claimed invention is unpredictable.

The teachings of Gonzalez-Hernandez et al. (2007) *Scand. J. Immunol.* 65:368-75, cited by the Examiner, merely point out that a certain subset ofT cells, which represent less than 20 percent of circulating T cells, secrete IFN-gamma, the hallmark Thl cytokine, in acute asthma attacks. Such an observation does not, however, necessarily negate the significance of skewing an immune response toward Thl in order to treat an allergic disease. Neither does it negate the significance of inducing T regulatory cells in order to treat an allergic disease. Accordingly, the teachings of Gonzalez-Hernandez et al. do not support the suggestion by the Examiner that the claimed invention is unpredictable.

Also on page 5 of the Office Action the Examiner cites Mamessier et al. (2006) *Eur. J. Dermatol.* 16:103-13 for the proposition that trying to alter the Thl/Th2 balance to treat allergy is not straight-forward. While Mamessier et al. does teach that targeting Th2 cytokines for allergic therapy has been inconsistent, such teaching is not relevant because it is limited to anti-IL-4 antibodies, anti-IL-5 antibodies, and anti-IL-5 receptor antibodies. The claimed invention is not so limited, and in fact Mamessier et al. goes on to teach both that Thl induction and IL-10-

producing cells (T regulatory cells) are preferred methods for treating allergic diseases. (See pages 109-111 of that reference.) Accordingly, the teachings of Gonzalez-Hernandez et al. do not support the suggestion by the Examiner that the claimed invention is unpredictable.

At the bottom of page 5 of the Office Action the Examiner asserts that the specification does not disclose adequate support for any isolated polymer which comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA). The Examiner cites Kalka-Moll et al. (2000) J. *Immunol.* 164:719-24 for the proposition that the recited polymer encompasses species that would not work in the claimed invention. Applicant wishes to point out in response that not every possible embodiment is required to work in order to satisfy the enablement requirement. In addition, the specification not only includes detailed disclosure of a number of polymers that are useful (see, for example, pages 39 - 44) but also incorporates by reference the teachings of U.S. Pat. Nos. 5,679,654 and 5,700,787, as well as published international patent applications WO 96/07427, WO 00/59515, and WO 02/45708, which disclose such polymers. (See page 1 of the specification.)

On page 6 of the Office Action the Examiner asserts that the term "comprising" in claim 1 widens the scope of the claim to include polymer species that include additional molecules that may impact the ability of the polymer to treat the allergic disease. While it is true that "comprising" is open language, it is standard to use such open language in claiming an invention and this cannot form the basis for an enablement rejection.

On page 7 of the Office Action the Examiner asserts that there is a great degree of unpredictability in the art as to how these polymers work. Applicant wishes to point out in response that knowledge of mechanism of action is not a requirement for enablement.

Also on page 7 of the Office Action the Examiner asserts that the recitation of a patient who is free of symptoms otherwise calling for treatment with the polymer is not enabled. Applicant directs the Examiner's attention to the passage at page 13, beginning at line 17, of the specification, where a large number of other conditions that can be treated using a polymer of the invention are disclosed. These same conditions are further described in U.S. Pat. Nos. 5,679,654 and 5,700,787, as well as published international patent applications WO 96/07427, WO 00/59515, and WO 02/45708, the contents of which are incorporated by reference into the disclosure of the invention.

At the bottom of page 7 of the Office Action the Examiner asserts that the term "anti-IgE" is not enabled. Applicant submits that the term "anti-IgE" plainly refers to an antibody that binds specifically to IgE, as evidenced by reference made to omalizumab (XOLAIR®, Genentech/Novartis) at page 19, lines 2-3 of the specification.

Finally, the Examiner asserts on pages 7-8 of the Office Action that the recitation of "administering comprises delivering an aerosol of the polymer to an airway of the subj ect" is not enabled because it is highly unpredictable that administration of the polymer to the airway of the subject will treat all allergic diseases, including contact dermatitis and food allergy. Applicant submits that aerosol delivery to an airway is an accepted method for systemic delivery of various agents. Passages on pages 32 - 36 of the specification describe how to prepare and use aerosol delivery devices to take advantage of this route of administration."

It remains the Examiner's position the specification does not disclose any examples of PSA1 being used to treat any allergic disease other than asthma, including urticaria, in any

patient, so there is no support in the specification for a method of treating an allergic disease other than asthma. The prior art shows that the genus of all allergic diseases encompass diseases with widely varying etiologies and pathologies and that one method of treatment is not sufficient to treat all allergic diseases. Because the art is highly unpredictable as to what will be a therapy for any particular allergic disease, much less all allergic diseases in all patients and because the specification has provided no guidance as to what polymers can be used to effectively treat any particular allergic disease the recited claims are not enabled .

It also remains the Examiner's position that the specification does not disclose adequate support for any isolated polymer which comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate. This recitation encompasses both molecules which have as yet been discovered and molecules which have been discovered which inherently possess these physiochemical properties. The recited polymer also encompasses peptides without disclosing the peptide sequences that would be encompassed by the claimed invention. Further, the description encompasses many species that the art shows would not work in the claimed invention (In particular, see Kalka-Moll et al.; IDS filed on 06/21/2004). Therefore, since the recited polymer encompasses species that would not work in the claimed invention, known species with this undiscovered physiochemical characteristic and polymers species that are currently unknown, practicing the method is highly unpredictable and it would require an undue amount of experimentation by one of ordinary skill in the art. The examples in the specification encompass treating asthma include PSA1 and CP1, but support for the terms 'polysaccharide' or

'capsular polysaccharide' in a method of treating an allergic condition other than asthma is not adequately disclosed. Further, the term 'comprising' in claim 1 is open language which widens the scope of the claim to include polymer species that include additional molecules. As recited, the method for treating an allergic disease other than asthma could be the result of the interaction of the additional part(s) of the molecule and not due to the zwitterionic polymer portion at all. In addition, one of ordinary skill in the art would not know what can be added to the recited polymer that will not impact the ability of the polymer to treat allergic disease. Contrary to Applicant's assertion this is a proper basis for an enablement rejection, irrespective of common use of the work comprising in claim language. The genus of polymers encompassed by the instant recitation is limitless. Therefore, accordingly, one of ordinary skill in the art would not know how to make and use the polymer genus for use in the claimed invention.

The claims are still not enabled for treating a patient who is free of "symptoms otherwise calling for treatment with the polymer." The symptoms associated with this need are not adequately disclosed such that one of ordinary skill in the art would know what what symptoms are encompassed. As discussed *supra* very little is know about these polymers and what they can treat, so defining a symptom that calls for treatment with the polymer in not predictable.

The term 'anti-IgE' is not enabled. . There is no support in the specification for all such molecules. Applicant's argument that one of ordinary skill in the art would know that "anti-IgE" refers to an antibody is not persuasive. The braadest reasonable interpretation of the term is a encompasses any molecule whose action opposes that of any IgE with any specificity. The

Examiner suggests amending the claim to recite the word 'antibody."

Further, the recitation of administering comprises delivering an aerosol to of the polymer to an airway of the subject to treat diseases other than asthma is not enabled. It is highly unpredictable that administration of the polymer to the airway of the subject will treat all allergic diseases, including contact dermatitis and food allergy. Therefore, it would require an undue amount of experimentation by one of ordinary skill in the art to determine what allergic diseases will be treated by an aerosol delivery mode of administration other than asthma or another respiratory disease.

Applicant argues that the mode of action is not necessary for enablement, but that argument is not persuasive. Rather, for the claims to be enabled, one of ordinary skill in the art must be able to make and used the invention commensurate in scope with the claims. Therefore, given this unpredictability, it would require an undue amount of experimentation for one of ordinary skill in the art to practice the claimed invention commensurate in the scope with the claims which recite treating any allergic disease other than asthma in any patient.

9. Claims 1-7 and 17-18 stand and claim 101 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of treating asthma in a mouse by injecting the mouse with isolated PSA1.

Applicant is not in possession of: a method for treating **an allergic condition other than asthma** in **a subject**, comprising: administering to **a subject** having an allergic condition other than asthma **an isolated polymer** in an effective amount to treat the allergic condition, wherein the polymer **comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate** of claim 1; wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate of claim 2; wherein the administering comprises **delivering an aerosol of the polymer to an airway of the subject** of claim 3; wherein the subject is **free of symptoms otherwise calling for treatment with the polymer** of claim 4; wherein the polymer is **a polysaccharide** of claim 5; wherein the polymer is **a bacterial capsular polysaccharide** of claim 6; wherein the polymer is PSA1 of claim 7; wherein the method further comprises administering to **the subject** an anti-allergy medicament selected from the group consisting of glucocorticoids, antihistamines, and **anti-IgE** of claim 17; wherein the administering comprises administering to **the subject** having **an allergic condition other than asthma** multiple doses of the **isolated polymer** to treat **the allergic condition** of claim18; and wherein the allergic condition other than asthma is urticaria of claim 101 for the same reasons as set forth in the Office Action mailed on 05/18/2007.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> According to the Examiner, the specification does not adequately describe any examples of PSA1 being used to treat any allergic disease other than asthma in any patient. Applicant points out that in addition to the fact that working examples are not required, the specification discloses a representative number of different polymers, allergic diseases, dosing and routes of administration, sufficient to convey to the skilled person that Applicant in fact had possession of the claimed invention at the time the application was filed. See, for example, specification at page 12, lines 13-16 (allergic conditions); pages 1 and 39 - 44 (polymers); and pages 44 - 47 (dosing and administration).
>
> On page 10 of the Office Action the Examiner asserts the use of the term "comprising" in claim 1 widens the scope of the claim to include polymer species that include additional molecules. Applicant submits that the disclosure makes clear that, surprisingly, specific but rather minimal structural requirements are sufficient to determine which polymers are useful according to the claimed method. While it is true that "comprising" is open language, it is standard to use such open language in claiming an invention and this cannot form the basis for a written description rejection as suggested by the Examiner.
>
> On page 11 of the Office Action the Examiner asserts that the terms "polysaccharide", "capsular polysaccharide", "patient who is free of symptoms otherwise calling for treatment with the polymer", and "anti-IgE" are not adequately described. For the sake of brevity, Applicant refers the Examiner to passages in the specification pointed out above in connection with these terms as raised in the enablement rejection. Applicant respectfully submits these terms are adequately described."

It remains the Examiner's position that the specification does not adequately describe any isolated polymer which comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate. The specification also does not adequately describe the

terms 'polysaccharide' or 'capsular polysaccharide' in a method of treating an allergic condition other than asthma. Further, the term 'comprising' in claim 1 is open language which widens the scope of the claim to include polymer species that include additional molecules. These recitations encompasses both molecules which have as yet been discovered; molecules which have been discovered which inherently possess these physiochemical properties; peptides without disclosed sequences and polymers whose result is due to the interaction of the additional part(s) of the molecule and not due to the zwitterionic polymer portion at all. The specification does not adequately described the genus of polymers that can be used in the claims invention to have the requisite function of treating an allergic condidtion.

The recitation of a patient who is free of symptoms otherwise calling for treatment with the polymer is also not adequately described. As discussed *supra* very little is know about these polymers and what they can treat, so how would you define a symptom that calls for treatment with the polymer.

The term 'anti-IgE' is not adequately described. The term encompasses any molecule whose action opposes that of any IgE with any specificity. There is no support in the specification for all such molecules.

It is the Examiner's position that the specification has not adequately described a correlation between function (treats an allergic condition other than asthma) and structure responsible for treating an allergic condition other than asthma such that one of ordinary skill in

the art would have known which polymers could be used to generate the disclosed function of treating an allergic condition other than asthma. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See University of Rochester, 358 F.3d at 927, 69 USPQ2d at 1895. "Without a correlation between structure and function, the claims do little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement." Ex parte Kubin, 83 U.S.P.Q.2d 1410 (BPAI 2007). The specification does not adequately describe the genus of all polymers for use in the claimed invention.

Contrary to Applicant's assertion, one of ordinary skill in the art would not be able to determine which polymers would work in the claimed invention since neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus of polymers that would work to treat an allergic condition other than asthma in the claimed invention. Applicant's assertion that all polymers would work is not supported by examples or description in the specification. Further, the art shows that not all polymers encompassed by the instant claim recitations are able to stimulate cellular immunity. No such structure requisite structure associated with the disclosed function has been described in the specification.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-2, 4-6, and 18 stand rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/075953 (IDS filed on 06/21/2004, Reference B3) as evidenced by the specification in original claim 10, now canceled for the same reasons as set forth in the Office Action mailed on 05/18/2007.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

"Without conceding to the Examiner's position and solely in the interest of expediting prosecution, Applicant has amended claim 1 to include the limitation "wherein the allergic condition is not eczema". Basis for this amendment can be found, for example, at page 12, lines **13-16** of the specification, where it is disclosed that allergic conditions include but are not limited to allergic asthma, hayfever (seasonal rhinitis), allergic rhinitis, allergic conjunctivitis, eczema, urticaria, food allergies, and other atopic diseases. "If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d

1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ('[the] specification, having described the whole, necessarily described the part remaining'.)." Applicant respectfully submits that by excluding eczema from claim 1, claim 1 is novel over WO 03/075953 because the only allergic disease other than asthma disclosed in that reference is eczema. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-2, 4-6, and 18 under 35 U.S.C. 102(e) as being anticipated by WO 03/075953."

It is the Examiner's position that the reference also teaches a method of treating acute respiratory distress syndrome, which is an allergic condition other than asthma and eczema. Therefore the rejection is maintained.

12. Claims 1-2, 4-6, and 18 stand rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0119164 (PTO-892, Reference A) as evidenced by the specification in original claim 10, now canceled for the same reasons as set forth in the Office Action mailed on 05/18/2007.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

"Without conceding to the Examiner's position and solely in the interest of expediting prosecution, Applicant has amended claim 1 to include the limitation "wherein the allergic condition is not eczema". Basis for this amendment can be found, for example, at page 12, lines **13-16** of the specification, where it is disclosed that allergic conditions include but are not limited to allergic asthma, hayfever (seasonal rhinitis), allergic rhinitis, allergic conjunctivitis, eczema, urticaria, food allergies, and other atopic diseases. "If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson,* 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ('[the] specification, having described the whole, necessarily described the part remaining'.)." Applicant respectfully submits that by excluding eczema from claim 1, claim 1 is novel over WO 03/075953 because the only allergic disease other than asthma disclosed in that reference is eczema. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-2, 4-6, and 18 under 35 U.S.C. 102(e) as being anticipated by WO 03/075953."

It is the Examiner's position that the reference also teaches the a method of treating acute respiratory distress syndrome, which is an allergic condition other than asthma and eczema. Therefore the rejection is maintained.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-7 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/59515 (IDS filed on 06/21/2004) in view of Tang et al. (PTO-892, Page 2, Reference U) for the same reasons as set forth in the Office Action mailed on 05/18/2007.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> "Applicant respectfully requests reconsideration. WO 00/59515 does not teach or suggest Th2 to Th1 switching. Instead, WO 00/59515 teaches what is common among many immune stimulatory molecules, that is, that the polymers disclosed in WO 00/59515 induce the production of both Th1 and Th2 cytokines. The mere presence of both Th1 and Th2 cytokines is not an indication that one or the other will be favored.
>
> WO 00/59515 teaches at page 26, lines 20-30, that the polymers induce IL-10. As stated, IL-10 "is considered to be a key Th2 cytokine which is known to inhibit Th1 function." WO 00/59515 also teaches, as cited by the Examiner, that the polymers induce IL-2, which is a Th1 cytokine, and therefore may be used to treat Th1-responsive

> disorders. WO 00/59515 does not, however, suggest that the polymers will cause a predominant Thl cytokine response and a Th2 to Thl shift.
>
> Tang et al. teaches that macrophages in the lung are responsible for directing a Thl- predominant response and antagonize the Th2 response of an inhaled antigen. Tang et al. also teaches on page 1480, at the end of the first full paragraph, that IL-10 is a cytokine necessary for Th2 proliferation, suggesting that IL-10 would favor a Th2 response.
>
> Therefore, WO 00/59515, either alone or in combination with Tang et al., does not suggest that the polymers would shift from Th2 to Thl and be useful to treat allergy. Instead, the combination, if anything, suggests not to use the polymers of WO 00/59515 to treat allergy because of the induction by the polymers of IL-10, known in the art and taught by Tang to be responsible for Th2 stimulation."

It is the Examiner's position that WO 00/59515 teaches treating Th1 responsive disorders with the same recited polymer. Further, column 23, line 60 to column 24, line 7 teaches that riving the immune response toward a Th1 response when it is desirable to have a Th1 cytokine response to treat disease, as is the case for allergies. Therefore, applicant's argument is unpersuasive.

15. Claims 1-7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,026,285 (PTO-892, Reference B) in view of Tang et al. (PTO-892, Page 2, Reference Y) for the same reasons as set forth in the Office Action mailed on 05/18/2007.

Applicant's arguments filed on 11/19/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> "The Examiner rejected claims 1-7 and 18 under 35 U.S.C. 103(a) as unpatentable over U.S. Patent 7,026,285 in view of Tang et al. *(supra)*. Applicant respectfully requests reconsideration. The cited patent is the U.S. equivalent of WO 00/59515. The rejection should be withdrawn for the same reasons as discussed above in connection with WO 00/59515.
>
> Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-7 and 18 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,026,285 in view of Tang et al. "

It is the Examiner's position that U.S. patent 7,026,285 teaches treating Th1 responsive disorders with the same recited polymer. Further, on page 31, lines 13-17, the reference teaches driving the immune response toward a Th1 response when it is desirable to have a Th1 cytokine response to treat disease, as is the case for allergies. Therefore, applicant's argument is unpersuasive.

16. No claim is allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 4, 2008
Nora M. Rooney, M.S., J.D.
Patent Examiner
Technology Center 1600

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644